

EXPRESS MAIL LABEL NO.: EV668788769US
DATE: November 6, 2006

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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER REGIM 3.3-069 |
| INTERNATIONAL APPLICATION NO. PCT/IB2004/001912 | | U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/556,641 |
| INTERNATIONAL FILING DATE 19 May 2004 | | PRIORITY DATE CLAIMED 20 May 2003 |
| TITLE OF INVENTION ORAL SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION | | |
| APPLICANT(S) FOR DO/EO/US Sandrine Salle and Emmanuel Guerin | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (Executed) 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). | | |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/556,641 | INTERNATIONAL APPLICATION NO. PCT/IB2004/001912 | ATTORNEY'S DOCKET NUMBER REGIM 3.3-069 | |
| 20. <input checked="" type="checkbox"/> Other items or information: Copy of Notification Of Missing Requirements Under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), Return Postcard | | | |
| The following fees have been submitted | | CALCULATIONS | PTO USE ONLY |
| 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300 | | \$ | |
| 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200 | | \$ | |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500 | | \$ | |
| TOTAL OF 21, 22 and 23 = | | \$ 0.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE |
| - 100 = | /50 = | | x \$250.00 |
| | | | \$ |
| Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ 130.00 | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE |
| Total claims | - 20 = | 0 | x 50.00 |
| Independent claims | - 3 = | 0 | x 200.00 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | + | |
| TOTAL OF ABOVE CALCULATIONS = | | \$ 130.00 | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | |
| SUBTOTAL = | | \$ 130.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ | |
| TOTAL NATIONAL FEE = | | \$ 130.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | \$ | |
| | | \$ | |
| TOTAL FEES ENCLOSED = | | \$ 130.00 | |
| | | Amount to be refunded: | \$ |
| | | Amount to be charged | \$ |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 12-1095 in the amount of \$ 130.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 12-1095. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:


SIGNATURE

Thomas M. Palisi

NAME

CUSTOMER NUMBER: 000530

36,629

REGISTRATION NUMBER

FDC



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

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|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/556,641 | Sandrine Salle | REGIM 3.3-069 |

00530
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DUE
17 DEC 2006
COLL

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| INTERNATIONAL APPLICATION NO. | |
| PCT/IB04/01912 | |
| I.A. FILING DATE | PRIORITY DATE |
| 05/19/2004 | 05/20/2003 |

CONFIRMATION NO. 8511
371 FORMALITIES LETTER
OC000000020850969

Date Mailed: 10/17/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 11/10/2005
- Copy of the International Search Report filed on 11/10/2005
- Preliminary Amendments filed on 11/10/2005
- Request for Immediate Examination filed on 11/10/2005
- U.S. Basic National Fees filed on 11/10/2005
- Priority Documents filed on 11/10/2005
- Specification filed on 11/10/2005
- Claims filed on 11/10/2005
- Abstracts filed on 11/10/2005
- Drawings filed on 11/10/2005

LDLK &M

OCT 20 2006

RECEIVED

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/556,641 | PCT/IB04/01912 | REGIM 3.3-069 |

FORM PCT/DO/EO/905 (371 Formalities Notice)